

DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration 158-15 Liberty Avenue Jamaica, NY 11433

WARNING LETTER

<u>CERTIFIED MAIL</u> <u>RETURN RECEIPT REQUESTED</u>

Mr. George Zulkofski President Jericho Cider Mill, Inc. 73 Route 106 Jericho, New York 11743 April 7, 2000

Ref.: NYK-2000-60

Dear Mr. Zulkofski:

An inspection of your facility at 73 Route 106, Jericho, New York, was conducted on February 22, 23 and 28, 2000 by U.S. Food and Drug Administration (FDA) Investigator Shari Kahn. During the inspection, samples of your Blackberry Spread, Apple Jelly and Orange Marmalade Preserve were collected for review of labeling.

Review of these labels revealed violations of the Nutrition Labeling and Education Act (NLEA) and Title 21, Code of Federal Regulations (CFR), part 101. More specifically, we have determined that these products are misbranded, in that they fail to bear nutrition labeling as required under Section 403 (q)(1) of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, CFR, Part 101.9. These products are not exempt from this requirement under Section 403 (q)(5) of the Act, and were labeled after May 7, 1997. We have no record in the official file showing the filing of a small business exemption from the nutrition labeling requirements for any low-volume food products produced and labeled by your firm.

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

Your should take prompt action to correct these label deficiencies. Failure to promptly correct these label deficiencies may result in regulatory action being initiated by FDA without further notice. These include seizure and injunction.

Please notify this office in writing with 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 15 working days, state the reasons and the time within which the corrections will be completed.

Jericho Cider Mill, Inc. Warning Letter NYK-2000-60

Your response should be sent to Lillian C. Aveta, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions, Ms. Aveta's telephone number is 718-662-5576.

Sincerely,

Brenda J. Holman District Director

Jericho Cider Mill, Inc. Warning Letter NYK-2000-60

cc:HFRNE1

cc:HFRNE100

cc:HFRNE140(LCA-2)

cc:HFR-NE140-QA

cc:Legal file

cc:HFRNE150

cc:HFRNE1500 (Vitillo/Kahn)

cc:HFS-607

cc:HFI-35

cc:EI (Jericho Cider Mill, Inc., cfn 2425146)

cc:HFA-224

cc:HFC-210 (cfn 2425146)

Facts: 2079-0

DCB approved: 4/7/00